

REMARKS & ARGUMENTS

After entry of this paper claims 1-14 and 46-57 are pending. Claims 55-57 are new. The disclosure supports the new and amended claims and the amendments thus add no new matter. Support for the new claims is found
5 throughout the disclosure with exemplary support as follows. Support for new claims 55 and 57 is at least at original claim 6 (thrombocytopenia). Support for new claim 56 is at least at page 88, lines 11-22 and page 326, lines 29-34 (R⁴ moieties, e.g., -NH₂ and configurations).

Although the Office referred to claims 1-15 and 46-53 as pending,
10 Applicant's file shows that claim 54 was included in the response to the prior restriction and is thus also pending.

Applicants have cancelled nonelected claims 15-45 to conform to the restriction requirement.

Applicants' records show that Applicants submitted information disclosure
15 statements to the Office on January 30, 2004 (73 references) and February 6, 2004 (76 references). The Office returned the postcard that accompanied the information disclosure statements, indicating that the Office received both statements. Applicants request entry of citations listed in these two statements into the record and their consideration by the Office.

20 Applicants enclose with this response a supplemental information statement and request entry of the listed citations into the record and their consideration by the Office.

35 U.S.C § 112, first paragraph

25 The Office objected to the specification and rejected claims 1-15 and 46-53 as allegedly not enabled. Applicants respectfully traverse the rejection.

To establish and maintain a rejection under 35 U.S.C. §112, first paragraph, the Office must provide logical reasoning to support its position. The Office must "explain why it doubts the truth or accuracy of any statement in a
30 supporting disclosure and to back up assertions of its own with acceptable

evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi and Horton*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). The Office must advance "substantive reasons why the instant specification is non-enabling." "Mere broad generalizations and allegations are insufficient for holding
5 of non-enablement." *Ex parte Goeddel* 5 U.S.P.Q. 2d 1449 (B.P.A.I. 1987). The first paragraph of 35 U.S.C. § 112 requires nothing more than objective enablement. *In Re Vaeck* 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991), *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.* 224 U.S.P.Q. 409 (Fed. Cir. 1984). It is irrelevant whether objective enablement is based on working examples or on
10 broad terminology. *In Re Vaeck*, supra, *Atlas Powder Co.*, supra. To meet the requirement under the first paragraph of § 112, the specification, when filed, must enable one skilled in the particular art to use the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988), *Ex parte Forman* 230 U.S.P.Q. 546 (B.P.A.I. 1986). In addition,
15 even if some of the claimed embodiments were inoperative, the claims are not necessarily invalid. "It is not a function of the claims to specifically exclude . . . possible inoperative substances" *Atlas Powder Co.*, supra, *In re Dinh-Nguyen*, 492 F.2d 856 (C.C.P.A. 1974).

The determination of what constitutes undue experimentation in a given
20 case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *In re Wands*, supra. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the
25 experimentation should proceed. *Ex parte Jackson, et al.*, 217 U.S.P.Q. 804 (B. P. A. I. 1982), *In re Ranier, et al.*, 146 U.S.P.Q. 218 (C.C.P.A. 1965). As explained below, Applicant respectfully submits that the specification enabled the claimed subject matter.

In casting the rejection, the Office stated: "The claims in referring to
30 substituted groups in the absence of the particular substituents are not

commensurate in scope with an enabling disclosure. The particular substituents are considered critical or essential to the practice of the invention.” Applicants request clarification of these statements. The Office’s point regarding substituents that are “considered critical” is simply not clear. Absent a reasoned
5 basis for casting the rejection, the Office should withdraw the rejection. *In re Marzocchi and Horton, supra*. In particular, the Office must provide a reason or rationale about why any particular substituent is critical. Absent some rationale, Applicants can only speculate about the specific basis for the rejection.

Applicants direct the Office’s attention to the teaching in the application,
10 including (1) example 38 beginning at paragraph 1270, which provides detailed protocols for modulating hematopoiesis, (2) examples 39 and 40 beginning at paragraphs 1283 and 1293, which provide detailed human clinical protocols for use of compounds within the scope of the claims, (3) the specification beginning at paragraph 602, which provides detailed discussion of methods to make,
15 prepare and use formulations that contain the compounds, and (4) the specification beginning at paragraph 602, which provides detailed discussion of treatments for blood cell deficiencies. Applicants respectfully request that the Office take into account the detailed teaching the specification contains.

Applicants direct the Office’s attention to the publication by D.R. Stickney,
20 et al. (40th Annual Meeting of the American Society of Clinical Oncology, Annual Meeting Proceedings vol. 23, abstract 6668, 2004, newly cited). The data in this publication shows that the compound recited in claims 53 and 56 has activity in treating both neutropenia and thrombocytopenia that is associated with either chemotherapy or radiation exposure. The methods described in that publication
25 closely mirror the methods contained in the present specification. Applicants have thus presented objective evidence that a compound within the scope of the claims has activity. As noted above, a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the
30 experimentation should proceed. *Ex parte Jackson, supra*. In view of the

foregoing, Applicants respectfully submit that the specification, including its detailed teaching enabled the claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants' representative can be reached at the number given below if
5 the Office has any questions or would like to address any other matters that may arise.

Respectfully submitted,

10 Dated: June 23, 2004

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Office Action Summary

Application No.

10/087,929

Applicant(s)

AHLEM ET AL.

Examiner

James M Spear

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 46-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 46-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's election of claims 1-15 and 46-53 in Paper filed November 17, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15 and 46-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wans*, 8 USPQ2d 1400 (Fed.Cir.1988). See MPEP2164.01(a). The claims in referring to substituted groups in the absence of the particular substituents are not commensurate in scope with an enabling disclosure. The particular substituents are considered critical or essential to the practice of the invention. When the Wans factors are weighed, it is the examiner's position that the disclosure fails to meet the enablement requirement. One skilled in the art could not practice the invention without undue experimentation.

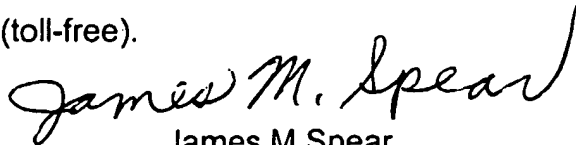
4. Claims 1-15 and 46-53 are rejected.

5. Claims 16-45 are withdrawn from consideration as being drawn to a non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James M Spear
Primary Examiner
Art Unit 1615

March 22, 2004